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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,215	02/20/2001	Martin Roland Jensen	3631-0107P	7660

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER
LI, RUIXIANG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,215	JENSEN ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 (in part), 2-29, and 33, drawn to a method for in vivo down-regulation of amyloid protein in an animal, wherein presentation of amyloidogenic polypeptide to the immune system is effected by introducing amyloidogenic polypeptide or its analogue into the animal cell, classified in class 435, subclass 7.1.

II. Claims 1 (in part) and 30-32, drawn to a method for in vivo down-regulation of amyloid protein in an animal, wherein presentation of amyloidogenic polypeptide to the immune system is effected by introducing nucleic acids encoding the modified amyoidogenic polypeptide or its analogue into the animal cell, classified in class 435, subclass 6.

III. Claims 1 (in part) and 47, drawn to a method for in vivo down-regulation of amyloid protein in an animal, wherein presentation of amyloidogenic polypeptide to the immune system is effected by administering a non-pathogenic microorganism or virus which is carrying a nucleic acid fragment which encodes and expresses the amyloidogenic polypeptide or analogue, classified in class 435, subclass 5.

IV. Claim 34, drawn to a method for treating and/or preventing Alzheimer's disease or other diseases and conditions characterized by amyloid deposits, classified in class 514, subclasses 2 and 12.

V. Claims 35-37, drawn to an analogue of an amyloidogenic polypeptide and an immunogenic composition comprising the same, classified in class 530, subclass 350; class 530, subclass 300.

VI. Claims 38-46 and 48-50, drawn to a nucleic acid fragment, a vector, a host cell, and a method for the preparation of the cell, classified in class 536, subclass 23.5; class 435, subclasses 320.1 and 325.

VII. Claim 51 (in part), drawn to a method for the identification of a modified amyloidogenic polypeptide which is capable of inducing antibodies, wherein the polypeptide is prepared by peptide synthesis and presented to the cell, classified in class 435, subclass 7.1.

VIII. Claim 51 (in part), 53, and 54, drawn to a method for the identification of a modified amyloidogenic polypeptide which is capable of inducing antibodies, wherein the polypeptide is prepared by genetically engineering techniques and is presented to the cell by introducing nucleic acid sequence(s) encoding a modified amyloidogenic polypeptide, classified in class 435, subclass 6.

IX. Claim 52 and 55-57, drawn to a method for preparation of an immunogenic composition comprising at least one modified amyloidogenic polypeptide, classified in class 514, subclasses 2 and 12.

2. The inventions are distinct, each from the other for the following reasons. Inventions I-IV, VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant

case, the different inventions are drawn to completely different methods each having completely different method steps and having completely different outcomes. Each method is unique and not required for another. Thus, the methods are exclusive and require non-cohesive searches and considerations.

3. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different products, analogues of an amyloidogenic polypeptide and nucleic acid molecules. These molecules have completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations.
4. Invention V is related to Inventions I-IV and VII-IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instant case, an analogue of an amyloidogenic polypeptide can be used to determine epitopes recognized by a T helper lymphocyte or by an antigen presenting cell.
5. Invention VI is related to Inventions II-IV and VIII as product and process of use. The invention can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP §806.05 (h)). In the instant case, the nucleic acid may be used in a materially different process such as production of an analogue of an amyloidogenic polypeptide.

6. Invention VI is an independent invention from Inventions I, VII, and IX. The different inventions are drawn to distinct product and method inventions.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to patentably distinct species: (i) Claim 1 contains two species: (a) amyloidogenic polypeptide/subsequence and (b) analogue of amyloidogenic polypeptide. (ii) Claim 3 contains 4 species (ways) of modification of amyloidogenic polypeptide, as listed in the claim. (iii) Claim 11 contains 5 species of tetanus toxoid epitopes. (iv) Claim 12 contains two species of the first moiety, as listed in the claim. (v) Claim 13 contains a number of species of the second moiety, as listed in the claim. (vi) Claim 14 contains a number of species of third moiety, as listed in the claim. (vii) Claim 20 contains numerous species of amyloidogenic polypeptides, as listed in the claim. (viii) Claim 31 contains a number of species (forms) of the nucleic acids, as listed in the claim. These species are entirely different and require non-cohesive searches and considerations.

Should applicants elect a group containing these claims, applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if

one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
September 9, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER